

NOV 13 2006

## **510(k) SUMMARY**

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Assigned 510(k) number is K061718.

### **Submitter:**

INNOVACON Laboratories, Inc.  
4106 Sorrento Valley Boulevard  
San Diego, California 92121

Tel.: 858-535-2030

Fax: 858-535-2038

### **Date:**

June 16, 2006

### **Contact Person:**

Edward Tung, Ph.D.

### **Product Names:**

Innovacon® Spectrum II Test Card  
Innovacon® Spectrum II Test Card with Integrated Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup)

### **Common Name:**

Multi-drug Multi-line lateral flow immunochromatographic test for the simultaneous and qualitative detection of Amphetamine, Cocaine, Marijuana, Benzodiazepines, Tricyclic Antidepressants, Barbiturates, Morphine, Phencyclidine, Oxycodone, Propoxyphene, Methadone, Opiate, Methamphetamine, Buprenorphine and Methylenedioxymethamphetamine in urine.

**Regulation Name:**

Amphetamine, Cocaine, Marijuana, Benzodiazepines, Tricyclic Antidepressants, Barbiturates, Morphine, Phencyclidine, Oxycodone, Propoxyphene, Methadone, Opiate, Methylenedioxymethamphetamine, Buprenorphine and Methamphetamine test systems.

**Product Code:**

LDJ, DIO, DJC, DKZ, DJG, LCM, JXM, DJR, DIS, LFG, LAF, JXN

**Classification Number:**

21 CFR § 862.3870, 21 CFR § 862.3250, 21 CFR § 862.3610, 21 CFR § 862.3100,  
21 CFR § 862.3650, 21 CFR § 862.3170, 21 CFR § 862.3620, 21 CFR § 862.3150,  
21 CFR § 862.3910, 21 CFR § 862.3700

**Device Classification:**

The Amphetamine, Cocaine, Marijuana, Benzodiazepines, Tricyclic Antidepressants, Barbiturates, Morphine, Phencyclidine, Oxycodone, Propoxyphene, Methadone, Opiate, Methylenedioxymethamphetamine, Buprenorphine and Methamphetamine test systems have been classified as Class II devices with moderate complexity.

The Innovacon Spectrum II Test Card and Innovacon Spectrum II Test Card with Integrated Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup) are similar to other FDA-cleared devices for the qualitative and simultaneous detection of Amphetamine, Cocaine, Marijuana, Benzodiazepines, Tricyclic Antidepressants, Barbiturates, Morphine, Phencyclidine, Oxycodone, Propoxyphene, Methadone, Opiate, Methylenedioxymethamphetamine, Buprenorphine and Methamphetamine in human urine.

**Intended Use:**

The Innovacon Spectrum II Test Card and Innovacon Spectrum II Test Card with Integrated Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup) are rapid chromatographic immunoassays for the qualitative and simultaneous detection of Marijuana, Cocaine, Methylenedioxymethamphetamine, Amphetamine, Morphine, Opiates, Methadone, Methamphetamine, Phencyclidine,

Benzodiazepine, Oxycodone, Propoxyphene, Tricyclic Antidepressants, Buprenorphine and Barbiturate in human urine at the cutoff concentrations of:

1,000 ng/mL or 300 ng/mL for Amphetamine,  
300 ng/mL for Barbiturate,  
300 ng/mL for Benzodiazepines,  
300 ng/mL or 150 ng/mL for Cocaine,  
50 ng/mL for Marijuana,  
300 ng/mL for Methadone,  
500 ng/mL or 1,000 ng/mL for Methamphetamine,  
500 ng/mL for Methylenedioxymethamphetamine,  
300 ng/mL for Morphine,  
2,000 ng/mL for Opiates,  
100 ng/mL for Oxycodone,  
25 ng/mL for Phencyclidine,  
300 ng/mL for Propoxyphene,  
10 ng/mL for Buprenorphine, and  
1,000 ng/mL for Tricyclic Antidepressants.

Configurations of the Innovacon Spectrum II Test Card and Innovacon Spectrum II Test Card with Integrated Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup) can consist of any combination of the above listed drug analytes. They are intended for healthcare professionals including professionals at point-of-care sites.

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

### **Description:**

The Innovacon Spectrum II Test Card and Innovacon Spectrum II Test Card with Integrated Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup) are competitive binding, lateral flow immunochromatographic assays for the qualitative and simultaneous detection of Marijuana, Cocaine, Methylenedioxymethamphetamine, Amphetamine, Morphine, Opiates, Methadone, Methamphetamine, Phencyclidine, Benzodiazepine, Oxycodone, Propoxyphene, Tricyclic Antidepressants, Buprenorphine and Barbiturate in human urine at the cutoff concentrations of:

1,000 ng/mL or 300 ng/mL for Amphetamine,  
300 ng/mL for Barbiturate,  
300 ng/mL for Benzodiazepines,  
300 ng/mL or 150 ng/mL for Cocaine,  
50 ng/mL for Marijuana,  
300 ng/mL for Methadone,  
500 ng/mL or 1,000 ng/mL for Methamphetamine,  
500 ng/mL for Methylenedioxymethamphetamine,  
300 ng/mL for Morphine,  
2,000 ng/mL for Opiates,  
100 ng/mL for Oxycodone,  
25 ng/mL for Phencyclidine,  
300 ng/mL for Propoxyphene,  
10 ng/mL for Buprenorphine, and  
1,000 ng/mL for Tricyclic Antidepressants.

These tests can be performed without the use of an instrument.

A positive urine specimen will not generate a colored-line for the specific drug tested in the designated test region. A negative urine specimen or a urine specimen containing of Marijuana, Cocaine, Methylenedioxymethamphetamine, Amphetamine, Morphine, Opiates, Methadone, Methamphetamine, Phencyclidine, Benzodiazepine, Oxycodone, Propoxyphene, Tricyclic Antidepressants, Buprenorphine and Barbiturate at the concentrations below the designated cutoff levels will generate a colored line in the designated test region for the drug. To serve as a procedural control, a color line will always appear at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

#### **Unmodified ACON Devices:**

The Innovacon<sup>®</sup> Spectrum II Test Card and Innovacon Spectrum II Test Card with Integrated Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup) are a “modified” product format derived from the previously FDA-cleared ACON Spectrum Multi-drug Multi-line Drug Screen Test Card and 6 ACON Single DOA Tests. These seven legally marketed but unmodified devices and their 510(k) numbers under which they were previously cleared are listed in Table 1.

**Table 1. Unmodified ACON Devices with K Numbers and Product Codes.**

<b>Previously Cleared ACON Drug of Abuse Test</b>	<b>510(k) Number</b>	<b>Product Code</b>
ACON Spectrum Multi-Drug Multi-Line Drug Screen Test Card and Test Card with Integrated Split E-Z Key Cup	K031759	LDJ DIO DKZ DJG LCM JXM DJR DIS LFG
ACON COC-150 One Step Cocaine Test Strip/Test Device	K032903	DIO
ACON mAMP-500 One Step Methamphetamine Test Strip/Test Device	K033299	LAF
ACON PPX One Step Propoxyphene Test Strip/Test Device	K040445	JXN
ACON AMP 300 One Step Amphetamine Test Strip/Test Device	K041822	DKZ
ACON OXY II One Step Oxycodone Test Strip/Test Device	K043507	DJG
ACON BUP One Step Buprenorphine Test Strip/Test Device	K060466	DJG



Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

NOV 13 2006

Edward Tung, Ph.D.  
INNOVACON Laboratories, Inc.  
4106 Sorrento Valley Boulevard  
San Diego, California 92121

Re: k061718  
Trade/Device Name: Innovacon Spectrum II Test Card  
Innovacon Spectrum II Test Card with Integrated Cups (Innovacon  
014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022  
Cup or E-Z Start Multi-Drug Test Cup)  
Regulation Number: 21 CFR 862.3100  
Regulation Name: Amphetamine test system  
Regulatory Class: Class II  
Product Code: DKZ, DIS, JXM, LDJ, DIO, DJR, DJC, DJG, LFG, LCM, JXN  
Dated: October 20, 2006  
Received: October 23, 2006

Dear Dr. Tung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

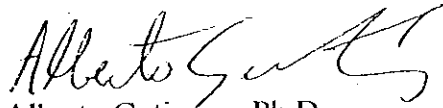
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

Page 2 –

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Alberto Gutierrez", with a stylized flourish at the end.

Alberto Gutierrez, Ph.D.

Director

Division of Chemistry and Toxicology

Office of In Vitro Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

## 10. INDICATIONS FOR USE

510(k) Number (if known):

Device Name: Innovacon Spectrum II Test Card  
Innovacon Spectrum II Test Card with Integrated Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup)

### Indications for Use:

The Innovacon Spectrum II Test Card and Innovacon Spectrum II Test Card with Integrated Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup) are rapid chromatographic immunoassays for the qualitative and simultaneous detection of Marijuana, Cocaine, Methylenedioxymethamphetamine, Amphetamine, Morphine, Opiates, Methadone, Methamphetamine, Phencyclidine, Benzodiazepine, Oxycodone, Propoxyphene, Tricyclic Antidepressants, Buprenorphine and Barbiturate in human urine at the cutoff concentrations of:

1,000 ng/mL or 300 ng/mL for Amphetamine,	300 ng/mL for Morphine,
300 ng/mL for Barbiturate,	2,000 ng/mL for Opiates,
300 ng/mL for Benzodiazepines,	100 ng/mL for Oxycodone,
300 ng/mL or 150 ng/mL for Cocaine,	25 ng/mL for Phencyclidine,
50 ng/mL for Marijuana,	300 ng/mL for Propoxyphene,
300 ng/mL for Methadone,	10 ng/mL for Buprenorphine, and
500 ng/mL or 1,000 ng/mL for Methamphetamine,	1,000 ng/mL for Tricyclic Antidepressants.
500 ng/mL for Methylenedioxymethamphetamine,	

Configurations of the Innovacon Spectrum II Test Card and Innovacon Spectrum II Test Card with Integrated Cups (Innovacon 014 Cup or E-Z Action Multi-Drug Test Cup and Innovacon 022 Cup or E-Z Start Multi-Drug Test Cup) can consist of any combination of the above listed drug analytes. They are intended for healthcare professionals including professionals at point-of-care sites.

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Prescription Use ... X ... AND/OR Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

  
Division Sign-Off

Office of In Vitro Diagnostic Device  
Evaluation and Safety

K061718